

REMARKS

The Office Action dated May 14, 2004 has been carefully considered. Claims 1-4, 11 and 12 are pending in the present application. Claims 5-10 and 13-44 are withdrawn. Reconsideration of the present application in view of the following remarks is respectfully requested.

I. CLAIM REJECTIONS UNDER 35 U.S.C. § 102(e)

Claims 1-4 and 12 are rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by U.S. Patent Application No. 2002/0068989 to Shanley et al. ("Shanley"). This rejection is respectfully traversed.

Independent claim 1 recites a "medical device for delivering a biologically active material to a body tissue of a patient in need of treatment, wherein the medical device comprises a plurality of struts and a plurality of non-structural elements integral with and projecting from the struts, wherein the struts and the non-structural elements comprise the biologically active material." Claims 2-4 and 12 depend upon claim 1 and therefore include all of the recitations of claim 1.

Shanley does not disclose or suggest "non-structural elements integral with and projecting from the struts" as recited in the present claims. The Examiner alleges that "Shanley discloses the invention as claimed noting figure 6 comprising: A medical device (which is a stent 10) with a plurality of struts (18) and a plurality of non-structural elements with *and projecting from* the struts (32), wherein the struts and the non-structural elements comprise the biologically active material. [00038]." (*See* Office Action, p. 2). However, it is respectfully submitted that element 32 in Shanley is not a non-structural element integral with and projecting from the strut as presently claimed. (*See, e.g.*, page 8, line 20 of the specification, and Figs. 6-14.)

Shanley discloses that "at least one and preferably a series of openings 32 are formed at selected locations in the bridging elements 14, as shown in FIG. 6." (Para. 0047). (emphasis added). Shanley teaches that at least some of the openings may be loaded with a beneficial agent. (Para. 0050). The openings in Shanley are formed by laser drilling or other means. (Para. 0047)

Thus, Shanley merely removes material from the strut and, thus, does not disclose or suggest the inclusion of non-structural elements integral with and projecting from the struts as recited in the present claims. It is respectfully submitted that the "opening" disclosed in Shanley is not a non-structural element and therefore cannot be considered to be a non-

structural element integral with and projecting from the strut. By disclosing an “opening” which is an absence of material, Shanley teaches away from the medical device of the present invention which includes, in addition to the struts, non-structural elements integral with and projecting from the struts.

Therefore, Shanley does not disclose or suggest, and, in fact, teaches away from the use of non-structural elements.

Thus, it is believed that claim 1 and the claims depending thereon are patentable over Shanley. Accordingly, withdrawal of this rejection and allowance of claims 1-4 and 12, are respectfully requested.

II. CLAIM REJECTIONS UNDER 35 U.S.C. § 103(a)

Claim 11 has been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Shanley in view of U.S. Patent No. 6,506,437 to Harish *et al.* (“Harish”). This rejection is respectfully traversed.

Claim 11 depends upon claim 1, which recites that “the medical device comprises a plurality of struts and a plurality of non-structural elements integral with and projecting from the struts, wherein the struts and the non-structural elements comprise the biologically active material.” Claim 11 further recites that “the biologically active material is selected from the group consisting of paclitaxel, actinomycin, sirolimus, tacrolimus, everolimus, dexamethasone, halofuginone and hydrophobic nitric oxide adducts.” Since claim 1 was shown above to be patentable over Shanley, it is believed that claim 11, which depends upon claim 1, is also patentable over Shanley. As stated above, Shanley does not disclose or suggest the use of non-structural elements integral with and projecting from the struts.

Harish does not remedy the deficiencies of Shanley. Harish discloses a device that has depots formed in the outer surface thereof. (Col. 3, lines 32-33). Also, Harish discloses applying a composition including a therapeutic substance into the depots. (Col. 2, lines 19-20). However, the depots are not non-structural elements integral with and projecting from the struts. (*See, e.g.*, Figure 3B). The depots of Harish are not non-structural elements since they are formed from the removal or absence of material in the outer surface of the device. Therefore, Harish does not disclose or suggest (1) a non-structural element integral with and projecting from the struts; and (2) struts and a non-structural element that comprises a biologically active material, as recited in the present claims.

Thus, Shanley and Harish, taken alone or in combination, do not disclose or suggest non-structural elements that are integral with and project from the struts. There is no motivation in the disclosures of Shanley and Harish to combine the teachings of these references to obtain the presently-claimed invention where Shanley and Harish both do not disclose non-structural elements that are integral with and project from the struts.

Accordingly, it is believed that claim 11 is patentable over Shanley and Harish. Thus, withdrawal of this rejection and allowance of claim 11 is respectfully requested.

III. CONCLUSION

Since all rejections to the claims are believed to be overcome, all claims are believed to be in condition for allowance. An early notice to that effect would be appreciated. Should the Examiner not agree with Applicant's position, then a personal or telephonic interview is respectfully requested to discuss any remaining issues and expedite the eventual allowance of the application.

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Respectfully submitted,

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